UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

Plaintiff,

- against -

N.Y. FISH, INC., a corporation, NEW YORK CITY FISH, INC., a corporation, MAXIM KUTSYK, an individual, PAVEL ROYTKOV, an individual, LEONID STAROSELETSKY, an individual, and STEVEN KOYFMAN, an individual,

Defendants.

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MEMORANDUM AND ORDER ON BENCH TRIAL AND MOTION FOR INJUNCTIVE RELIEF

13-CV-2909 (RRM)

ROSLYNN R. MAUSKOPF, United States District Judge.

The United States seeks to enjoin two seafood production companies and their senior management from producing food products at a facility in Brooklyn alleged to be noncompliant with the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. The government filed its complaint on May 17, 2013, alleging that defendants had violated 21 U.S.C. §§ 331(a) and (k) by introducing adulterated food into interstate commerce and by causing food to become adulterated while held for sale after the shipment of one or more components in interstate commerce. (*See* Doc. No. 1.) At that time, the government requested a preliminary injunction prohibiting defendants from further violations of those provisions. (*See* Doc. No. 2.)

On May 23, 2013, this Court ordered defendants to show cause why the government's application for preliminary injunctive relief should not be granted.[1] After briefing by the parties and with their consent, the Court consolidated the motion for a preliminary injunction with a

[1] Despite the government's repeated efforts to provide notice, defendants N.Y. Fish, Inc., and Koyfman have failed to appear or otherwise respond throughout this litigation. As such, except where noted, references to defendants pertain only to the appearing defendants New York City Fish, Inc., Kutsyk, Roytkov, and Staroseletsky.

bench trial on the merits. *See* Fed. R. Civ. P. 65(a)(2). Trial was held from July 9–10, 2013, during which the Court heard testimony from Peter M. Trunk, the FDA investigator who inspected the Chester Street facility in February 2013; Mary E. Losikoff, a Consumer Safety Officer in the Division of Seafood Safety at the FDA; Frank Costanzo, a seafood safety and regulatory compliance consultant retained by defendants; defendant Roytkov; and defendant Kutsyk. For the reasons that follow, the government's motion for injunctive relief is granted, with a directive to modify the proposed order of permanent injunction consistent with this opinion.[2]

BACKGROUND

As the findings of fact recounted below demonstrate, from about January 2006 through September 2012, defendant N.Y. Fish, Inc. ("N.Y. Fish"), a New York corporation, had its principal place of business at 738 Chester Street in Brooklyn, New York ("the Chester Street facility"). N.Y. Fish had a troubled history with the U.S. Food and Drug Administration ("FDA"). Between 2006 and 2012, the FDA conducted six inspections of the Chester Street facility and discovered violations of the FDCA each time. (*See generally* Decl. of Ronald M. Pace ("Pace Decl.") (Doc. No. 13).)[3] Most significantly, during that period environmental samples collected from various locations within the facility and from finished fishery products

[2] On August 8, 2013, almost a month after the close of evidence at trial, defendants moved for leave to submit additional evidence. (*See* Doc. No. 47.) On November 21, 2013, defendants again requested leave to submit newly collected evidence. (*See* Doc. No. 58.) These motions are denied for substantially the reasons asserted by the government in its opposition to granting leave. (*See* Doc. Nos. 53, 57.) Even setting aside the question of whether defendants' evidence has any probative value, defendants have offered no factual reasons why it could not have been collected prior to the close of evidence or any persuasive legal justification for granting leave.

[3] Prior to trial, the parties consented to the adoption of the Pace Declaration by Losikoff, who was competent to testify to the information contained in the declaration and appeared as a witness subject to cross-examination at trial. (*See* Tr. of Proceedings on July 9–10, 2013 ("Tr.") (Doc. Nos. 51–52), at 34:14–35:3.)

tested positive for *Listeria monocytogenes* ("*L. mono*").[4] Several of the *L. mono* strains isolated at the Chester Street facility were found to persist from inspection to inspection.

N.Y. Fish ceased operations sometime in September 2012, leaving behind its processing logs, Hazard Analysis and Critical Control Point ("HACCP")[5] and Sanitation Standard Operating Procedure ("SSOP")[6] plans, records, fixtures, and equipment. Throughout October 2012, the Chester Street facility apparently sat vacant. During that month, however, defendant Kutsyk incorporated New York City Fish, Inc. ("N.Y.C. Fish"), which then leased the Chester Street facility and began operations on or about November 1, 2012. Like N.Y. Fish before it, N.Y.C. Fish prepares, processes, packs, holds, and distributes ready-to-eat smoked and cured fishery products, including salmon, mackerel, and herring. To staff his new company, Kutsyk hired a number of former N.Y. Fish employees.

[4] "*L. monocytogenes* is a bacterium that causes the disease listeriosis, and food contaminated with this bacterium is harmful to human health." *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 37 (E.D.N.Y. 2001), *aff'd*, 56 F. App'x 542 (2d Cir. 2003). Listeriosis can be serious and even fatal for certain groups such as the elderly, pregnant women, infants, and others with impaired immune systems. (*See* Decl. of Mary E. Losikoff ("Losikoff Decl.") (Doc. No. 1-3) ¶ 22.) In susceptible individuals, the most serious consequence of infection is septicemia, while more common problems include harm to the central nervous system, pneumonia, endocarditis, abscesses, lesions, and conjunctivitis. Complications for pregnant women can include miscarriage, stillbirth, meningitis, and bacteria in a newborn's bloodstream. Listeriosis can be treated with antimicrobial drugs, but it may be fatal for some individuals who become infected. *See Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 37.

[5] "HACCP is a management system designed to prevent the occurrence of potential food safety problems." *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 34. "Seafood processors are required to establish and implement HACCP plans pursuant to 21 C.F.R. § 123.6(b)." *Id.* Under the relevant regulations, a processor of fish and fishery products must assess the biological, chemical, and physical hazards at all stages of processing – from raw materials through distribution and consumption of the finished products – determine the necessary steps to control those risks, document their analyses in HACCP plans, and keep records of the monitoring of the actual values and observations during processing. *See* 21 C.F.R. § 123.6; *cf. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 34.

[6] Every seafood processor must also "have and implement a written sanitation standard operating procedure . . . or similar document that is specific to each location where fish and fishery products are produced." 21 C.F.R. § 123.11(a). An SSOP specifies how the processor will ensure sanitation conditions and practices that must be monitored "during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices . . . that are both appropriate to the plant and the food being processed," *id.* § 123.11(b), as well as certain enumerated regulatory factors.

In February 2013, an FDA inspection again documented significant HACCP and Current Good Manufacturing Practices ("CGMP")[7] violations. Kutsyk then retained Costanzo to provide advice concerning the procedures and systems necessary for the proper operation of a seafood factory. (Decl. of Frank Costanzo ("Costanzo Decl.") (Doc. No. 15) ¶ 22.) Costanzo inspected the facility, observed the current practices at N.Y.C. Fish, and reviewed the documents from the February 2013 and August 2012 inspections. Kutsyk asserts that, in consultation with Costanzo, he made a number of beneficial changes at the Chester Street facility.[8] The government maintains that these changes – if they were made at all – are insufficient to allay the FDA's concerns.

After briefing had been submitted on the issues in this case, the parties consented to a consolidation of the motion for preliminary relief with a bench trial on the merits. *See* Fed. R. Civ. P. 65(a)(2). Following trial, the parties submitted proposed findings of fact and conclusions of law, along with post-trial memoranda on all relevant issues. With the benefit of the record established at trial and the parties' submissions, the Court issues the following Findings of Fact and Conclusions of Law based on a preponderance of the evidence. *See* Fed. R. Civ. P. 52(a)(1) ("In an action tried on the facts without a jury . . . the court must find the facts specially and state its conclusions of law separately. The findings and conclusions . . . may appear in an opinion or a memorandum of decision filed by the court.").

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[7] Current Good Manufacturing Practices, set out in 21 C.F.R. Part 110, are regulations applicable to all food establishments regulated by the FDA and represent the minimum standards necessary under the FDCA to ensure the production of safe, wholesome foods. (*See* Losikoff Decl. ¶¶ 7–10.) "The criteria and definitions" that comprise CGMP "apply in determining whether a food is adulterated . . . ." 21 C.F.R. § 110.5(a).

[8] In particular, Kutsyk avers that he repaired a hole and broken tile above a fish processing table, as well as other damaged tiles; submitted revised HACCP plans for both hot- and cold-smoked products; purchased color-coordinated cleaning supplies; installed a new hose system for chlorinated foam to assist with cleaning; repaired the ovens; purchased and installed new temperature recording devices; repainted the floors; hung plastic room divider curtains; and purchased new chlorine dioxide activation and peroxyacetic acid ("PAA") systems. Kutsyk also notified the FDA that a product found to have an incorrect water phase salt content during the February 2013 inspection was air-packed, and therefore subject to a lower critical limit. (*See* Decl. of Maxim Kutsyk ("Kutsyk Decl.") (Doc. No. 14) ¶¶ 29–38.)

FINDINGS OF FACT[9]

In a bench trial, the Court "acts both as a determiner of whether a case meets the legal requirements for decision by a fact-finder and as a fact-finder." *Cabrera v. Jakabovitz*, 24 F.3d 372, 380 (2d Cir. 1994). "As the fact[-]finder, the [C]ourt is under a duty to weigh the evidence, determine the credibility of witnesses and draw whatever reasonable inferences the established facts may warrant." *United States v. Beigel*, 254 F. Supp. 923, 932 (S.D.N.Y. 1966), *aff'd*, 370 F.2d 751 (2d Cir. 1967); *see also Krist v. Kolombos Rest. Inc.*, 688 F.3d 89, 95 (2d Cir. 2012) ("It is within the province of the district court as the trier of fact to decide whose testimony should be credited."). "The obligations of the [C]ourt as the trier of fact are to determine which of the witnesses it finds credible, which of the permissible competing inferences it will draw, and whether the party having the burden of proof has persuaded it as fact[-]finder that the requisite facts are proven." *Cifra v. G.E. Co.*, 252 F.3d 205, 215 (2d Cir. 2001).

Upon due consideration and examination of the developed factual record, including the parties' declarations and affidavits, the testimony of witnesses at trial, and the exhibits introduced into evidence, the Court makes the following findings of fact:

1. Defendant N.Y. Fish is a New York corporation. From at least January 2006 to at least October 2012, N.Y. Fish's principal place of business was located at 738 Chester Street, Brooklyn, New York. During that time period, N.Y. Fish prepared, processed, packed, held, and distributed ready-to-eat smoked and cured fishery products, including salmon, mackerel, and herring, in the Chester Street facility.

2. Defendant N.Y.C. Fish is a New York corporation, with its principal place of business at the Chester Street facility. N.Y.C. Fish was incorporated in October 2012 and entered into a lease of the Chester Street facility in November 2012. N.Y.C. Fish prepares, processes, packs, holds, and distributes ready-to-eat smoked and cured

[9] To the extent that any of the following Findings of Fact may be deemed Conclusions of Law, or vice versa, they shall also be considered such conclusions. *See Miller v. Fenton*, 474 U.S. 104, 113–14 (1985) (noting the occasional difficulty of differentiating findings of fact from conclusions of law); *see also Int'l Union of Painters & Allied Trades, AFL-CIO v. Local 8A-28A*, No. 09-CV-4358 (RRM) (RLM), 2010 WL 3780366, at *1 n.1 (E.D.N.Y. Sept. 21, 2010).

fishery products, including salmon, mackerel, and herring, in the Chester Street facility.

3. N.Y.C. Fish began operating at the Chester Street facility on or about November 1, 2012. Prior to that date, the facility sat vacant following the cessation of business by N.Y. Fish.

4. N.Y.C. Fish hired and currently employs individuals who formerly worked at N.Y. Fish. Eight of N.Y.C. Fish's fourteen employees were formerly employed by N.Y. Fish.

5. Defendant Kutsyk, an individual, is the President of N.Y.C. Fish. He is responsible for all of N.Y.C. Fish's business operations and oversees all aspects of the firm, including purchasing raw materials and making final decisions regarding employees, equipment, and business matters. He performs his duties at the Chester Street facility.

6. Defendant Pavel Roytkov, an individual, is the Vice President of N.Y.C. Fish, and former Vice President of N.Y. Fish. In his capacity as Vice President of N.Y.C. Fish, Roytkov reports directly to Kutsyk, oversees the purchase of raw materials and other supplies needed for the manufacturing operations, and oversees certain aspects of the manufacturing operations. In his capacity as Vice President of N.Y. Fish, he reported directly to the president of N.Y. Fish, oversaw the purchase of raw materials and other supplies needed for the manufacturing operations, and oversaw certain aspects of the manufacturing operations. Additionally, Roytkov was responsible for conducting the official HACCP review of all critical control point and process schedule monitoring records to ensure that values were within critical limits. His duties at both N.Y. Fish and N.Y.C. Fish were and are performed at the Chester Street facility. Roytkov failed to inform his new employer of the longstanding problems the FDA found in N.Y. Fish's HACCP records, which N.Y.C. Fish continued to use.

7. Defendant Leonid Staroseletsky, an individual, is the Plant Manager of N.Y.C. Fish, and former Plant Manager of N.Y. Fish. In his capacity as Plant Manager of N.Y.C. Fish, he reports directly to Kutsyk, oversees all manufacturing operations including monitoring production of all batches from raw material to finished product, processing methods and cooking/smoking ovens, plant sanitation, and product labeling, oversees employee management, and manages all sanitation operations. Additionally, he prepares and initials the Brining and Temperature Logs for batches of finished product. In his capacity as Plant Manager of N.Y. Fish, he reported directly to Roytkov, oversaw all manufacturing operations, oversaw employee management, and managed all sanitation operations. Additionally, Staroseletsky prepared and initialed the Brining and Temperature Logs. Staroseletsky's duties at both N.Y. Fish and N.Y.C. Fish were and are performed at the Chester Street facility. Staroseletsky failed to inform his new employer of the longstanding problems the FDA found in N.Y. Fish's HACCP records, which N.Y.C. Fish continued to use.

8. Since November 2012, N.Y.C. Fish, Kutsyk, Staroseletsky, and Roytkov receive raw fish for their ready-to-eat fish products from outside of New York, including frozen mackerel from Rhode Island, and sell ready-to-eat fish products to stores in Maryland, Massachusetts, Pennsylvania, and New Jersey.

9. The ready-to-eat fish products produced by N.Y.C. Fish, Kutsyk, Staroseletsky, and Roytkov in the Chester Street facility since November 2012 are articles of food.

10. Prior to November 2012 and in their capacity as managers of N.Y. Fish, Staroseletesky and Roytkov received raw fish for their ready-to-eat fish products from outside of New York, including frozen mackerel from Rhode Island, and sold their food to stores in Maryland, Massachusetts, Pennsylvania, New Jersey, and Illinois.

11. The ready-to-eat fish products produced by Kutsyk and Roytkov in the Chester Street facility prior to November 2012 are articles of food.

12. The FDA has conducted seven inspections of the Chester Street facility between 2006 and 2013. The FDA inspections were conducted between February 12 and 15, 2013 ("February 2013 Inspection"); August 13 and 24, 2012 ("August 2012 Inspection"); October 28 and November 10, 2010 ("October–November 2010 Inspection"); October 10 and November 3, 2009 ("October–November 2009 Inspection"); May 27 and June 3, 2009 ("May–June 2009 Inspection"); September 10 and 26, 2008 ("September 2008 Inspection"); and January 11 and 23, 2006 ("January 2006 Inspection").

13. During the January 2006 Inspection, FDA investigators observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which Roytkov and Staroseletsky are responsible:

    a. Food residue on the cutting board surface of the vacuum packaging machine in the packing room, on the slicing machine used to cut ready-to-eat cold smoked salmon, and on the production knives and utensils used to process raw fish;

    b. Dirty lab coats stored next to and directly touching clean lab coats;

    c. Raw, thawed herring piled on top of a stainless steel production table and against a tiled wall directly touching chipped, exposed wall tile;

    d. Food residue on the stainless steel door and handle of the smoker oven and dried liquid on several plastic bags that are used to package ready-to-eat smoked fish;

    e. Chipped and broken wall tiles above and directly next to a stainless steel production table where ready-to-eat cold smoked salmon are staged;

f. An open bin filled with rinsed product stored next to and under chipped wall tiles;

g. Peeling and flaking paint on metal frames around eighteen ceiling lights;

h. A rusted ceiling frame;

i. Fish residue on the tiled walls, at the bottom of a metal door frame, and on a plastic stand used to hold clean buckets to package product;

j. Standing water behind the smoker oven;

k. The absence of calibration records indicating that the freezer thermometer had been calibrated as written in N.Y. Fish's HACCP plan; and

l. N.Y. Fish's HACCP plan failed to identify histamine as a food safety hazard.

14. In addition, during the January 2006 inspection FDA investigators collected environmental samples from various locations within the Chester Street facility. FDA analysis revealed the presence of *L. mono* in samples collected from floor drains in the primary and secondary processing rooms.

15. During the September 2008 Inspection, FDA investigators observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which Roytkov and Staroseletsky are responsible:

a. Food residue on the slicer and fish skinner, unsanitized floors, and smoked salmon on and around all processing equipment;

b. Standing water in the finished product refrigerator and in front of an oven where carts are transported;

c. An absence of records establishing that the fish received for processing was within the critical limits identified in the N.Y. Fish's HACCP plan; and

d. Critical control point monitoring lacking a HACCP-trained reviewer's signature and/or date.

16. During the September 2008 inspection, FDA investigators also collected environmental samples from various locations within the Chester Street facility. FDA analysis of these samples revealed the presence of *L. mono* in ten locations of the facility, including samples collected from floor drains, the slicer blade, the salmon skinner, the skinner table wheels in the packing room; the floor drain in the brining refrigerator; the floor drain in the cutting room; standing water in the finished product refrigerator and in the cutting room; and a discarded mop head in the hallway.

17. In addition, during the September 2008 inspection FDA investigators collected samples of finished fishery products. FDA analysis of these samples revealed the presence of *L. mono* in finished fishery products.

18. During the May–June 2009 Inspection, FDA investigators observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which Roytkov and Staroseletsky are responsible:

    a. Unclean and unsanitized equipment and utensils in the packaging room;

    b. Ready-to-eat, packaged and unpackaged, cold-smoked salmon exposed to ambient temperatures of 61°F from morning until afternoon in the packing room;

    c. Black residue at the ends of twenty-three potable water hoses placed directly into plastic totes of raw or brined whole fish;

    d. Food residue on the conveyer belt of the slicer, the housing components of the fish skinner, containers and scoops, stainless steel fish handing racks, hooks used to dry fish, and drying racks;

    e. Missing and/or cracked floor and wall tiles and cracked and pitted cement floors that prevent the plant from being adequately cleaned and sanitized;

    f. Colored substance resembling algae growth on the cracked ceiling tiles;

    g. Two stainless steel sinks in the pot wash room without waste pipes connected to the drains of each sink, allowing the waste water to fall from the sink to the floor drain in the center of the room; and

    h. Standing water on the floor at the entrance to the cleaning/cutting room.

19. During the May–June 2009 inspection, FDA investigators also collected environmental samples from various locations within the Chester Street facility. FDA analysis revealed the presence of *L. mono* in sixty of the environmental samples, including samples collected from aprons in the cutting room; a cracked floor tile in the smoke room; a missing floor tile in the pot wash hallway; a bucket of knives in the pot wash room; a refrigerator in the pot wash hallway; divider strips in the main hallway; a floor/wall junction in the rinse/hanging room; a drying rack in the brining refrigerator; and a floor drain cover in the drying room.

20. In addition, during the May–June 2009 inspection FDA investigators collected samples of finished fishery product, and FDA analysis of these samples revealed the presence of *L. mono*.

21. In June 2009, FDA investigators in Philadelphia and Chicago collected from one Pennsylvania retailer and two Illinois retailers, respectively, samples of finished fishery products manufactured at the Chester Street facility. FDA analysis of these samples revealed the presence of *L. mono* in the finished fishery products.

22. During the October–November 2009 Inspection, FDA investigators observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which Roytkov and Staroseletsky are responsible:

    a. The absence of receiving records establishing that the fish received for processing is within the critical limits identified in N.Y. Fish's HACCP plan;

    b. The absence of monitoring and cooling records to ensure that fish is stored at temperatures identified in N.Y. Fish's HACCP plan;

    c. Refrigerated storage, receiving, calibration and sanitation records that had not been signed or dated as reviewed;

    d. A section of white wall paneling partially detached from the wall at the floor junction;

    e. A metal door guide bracket on the brining refrigerator door in the rinsing/hanging room that was loose and sitting in standing water;

    f. Fans in the drying room coated with dirt and grime on the protective shields and positioned so that the air flow was directed at seafood products to facilitate drying;

    g. Several dividing brackets in the brining refrigerator which were dislodged from one end and hanging at various angles from the ceiling;

    h. Ceiling tiles in disrepair and coated with green and black spots;

    i. An accumulation of water beneath the floor tiles in the smoke oven room located within two feet of the smoke oven closest to the packing room;

    j. Food residue on the slicing machine and fish skinner after N.Y. Fish had cleaned and sanitized the equipment;

    k. Food residue on protective aprons hanging from a wall in the cutting/cleaning room; and

    l. Black residue within eight inches of the water supply hoses hanging from the ceiling of the cutting/cleaning room, rinsing/hanging room, and the brining refrigerator.

23. In addition, during the October-November 2009 Inspection FDA investigators collected environmental samples from various locations within the Chester Street facility. FDA analysis of those samples revealed the presence of *L. mono* in numerous locations in the facility, including a cutting room floor/wall junction; a cutting room surface/interior drain; a rinse/hanging room loose refrigerator door track; and a rinse/hanging room drain cover surface.

24. During the October–November 2010 Inspection, FDA investigators observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which Roytkov and Staroseletsky are responsible:

    a. Food residue on four cutting boards and on plastic tables in a room where fish is cut and cleaned;

    b. Plastic tables that employees had not cleaned or sanitized daily or routinely;

    c. A stainless steel table with small, closely-spaced rusted holes, which prevented adequate cleaning and sanitizing and through which food residue could drip to the table's underside;

    d. Sanitation monitoring records revealing that N.Y. Fish was not monitoring the sources of water used in the plant;

    e. Personal employee food items stored in a cooler on top of pickled herring pails and raw salmon;

    f. Contact between employees' lab coats and ready-to-eat fishery products;

    g. The absence of records on file from suppliers guaranteeing that the histamine hazard was either not present or below a certain level;

    h. A refrigeration unit that exceeded the critical limit of 38ºF identified in N.Y. Fish's HACCP plan;

    i. Corrective action plans in N.Y. Fish's HACCP plan that did not require the identification of the cause of process deviations; and

    j. Critical control point monitoring records lacking a HACCP-trained reviewer's signature and/or date.

25. In addition, during the October–November 2010 inspection FDA investigators collected environmental samples from various locations within the Chester Street facility. FDA analysis of the those samples revealed the presence of *L. mono* in numerous locations in the cutting room of the facility, including a table for a brine vat, three floor/wall junctions, and the part of a door where hand contact would be made.

26. During the August 2012 Inspection, FDA investigators observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which Roytkov and Staroseletsky are responsible:

    a. Food residue consisting of accumulating fat and pieces of ready-to-eat salmon on the slicing machine's conveyor lines, cutting blades, and blade height adjustment tracks;

    b. Brine being poured down a floor drain adjacent to a rack of whole salmon sides and splashing onto the bottom rack and salmon sides staged there;

    c. Dark grime and residue on the restroom floors and toilets;

    d. A women's restroom without running hot water;

    e. Employees drying their hands on outer garments or personal clothing before returning to the processing area;

    f. Broken floor tiles near the northeast corner of the slicing/packing room and at the entrance to the brining refrigerators that resulted in pooled water;

    g. An inadequately repaired floor/wall junction that accumulated water and dark-colored grime;

    h. A white ceiling tile that had fallen and exposed the vacuum packaging machines to falling debris;

    i. Laboratory analysis results revealing a water phase salt content in hot-smoked mackerel that was below the critical limit in N.Y. Fish's HACCP plan;

    j. Temperature recording charts revealing that the firm was not monitoring and recording internal fish temperatures during hot and cold smoking, even though N.Y. Fish's HACCP plan identified the internal fish temperature for a certain period of time as a critical control point;

    k. Temperature logs that were prepared and initialed by Staroseletsky and signed as reviewed by Roytkov, that stated that certain batches of hot-smoked fish had achieved the temperature and time critical limits identified in N.Y. Fish's HACCP plan even though the corresponding temperature recording charts revealed that those batches had not achieved the temperature and time critical limits identified in N.Y. Fish's HACCP plan;

    l. Brining logs revealing that smoked fish did not receive the minimum amount of brining time identified in N.Y. Fish's written HACCP plan;

m. N.Y. Fish's written HACCP plan with corrective action plans that did not require the identification of the cause of process deviations;

n. Critical control point monitoring records lacking a HACCP-trained reviewer's signature and/or date; and

o. Recording thermometer devices that had not been calibrated since being installed in 2010 even though the factory calibrations are good for only one year.

27. During the August 2012 inspection, FDA investigators also collected environmental samples from various locations within the Chester Street facility. According to N.Y. Fish, the Chester Street facility had been fully cleaned and sanitized prior to the collection. FDA analysis of those samples revealed the presence of *L. mono* in numerous locations in the facility, including the slicing machine; the floor drain where the brine was being poured; a floor/wall junction; a drain cover; and a hole in a tile floor where water was accumulating.

28. In addition, during the August 2012 inspection FDA investigators collected samples of in-process fishery products, specifically the staged salmon that was splashed with brine that an employee poured down the floor drain. FDA analysis of these samples revealed the presence of *L. mono* in the in-process fishery products.

29. During the February 2013 inspection, an FDA investigator observed the following, which, as set forth below in the Court's Conclusions of Law, constitute violations of the FDCA for which N.Y.C. Fish, Kutsyk, Roytkov, and Staroseletsky are responsible:

a. A hole in the wall of the draining room above a processing table where fish are staged;

b. Laboratory analysis results revealing that the water phase salt content in a batch of cold-smoked mackerel was below the critical limit in N.Y.C. Fish's HACCP plan;

c. Temperature recording chart records revealing that multiple batches of hot-smoked fish were heated for amounts of time that were below the critical limit identified in N.Y.C. Fish's HACCP plan;

d. Temperature logs that were prepared and initialed by Staroseletsky and signed as reviewed by Roytkov that stated that certain batches of hot-smoked fish achieved the temperature and time critical limits in N.Y.C. Fish's HACCP plan even though the corresponding temperature recording charts, which were also initialed by Staroseletsky, revealed that the heating of those batches did not achieve the temperature and time critical limits in N.Y.C. Fish's HACCP plan; and

e. Critical control point monitoring records lacking a reviewer's signature and/or date.[10]

30. Following the February 2013 inspection, Kutsyk retained Frank Costanzo, a seafood safety and regulatory compliance consultant, to provide advice and consultation in connection with the procedures and systems necessary and prudent for the proper operation of a seafood factory.

CONCLUSIONS OF LAW

The Court next turns to the legal principles applicable to this case. Having reviewed and considered the parties' arguments and submissions, the following constitute the Court's conclusions of law as to each defendant's liability for violations of the FDCA, as well as the government's entitlement to injunctive relief.

I. Legal Standard for a Statutory Permanent Injunction

The district courts of the United States have jurisdiction to restrain violations of section 331 of the FDCA "for cause shown." 21 U.S.C. § 332(a). "To enjoin future behavior, the government must show that defendants have violated the FDCA and that there is some reasonable likelihood that the violations may recur."[11] *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 50 (citing *Diapulse*, 457 F.2d at 28–29; *United States v. Schmitt*, 734 F. Supp. 1035, 1049 (E.D.N.Y. 1990)). A single violation provides a sufficient basis for the government to seek

[10] The FDA did not test for the presence of *L. mono* during the February 2013 inspection "[b]ecause [the FDA] had determined that the *L. mono* contamination detected during the six prior inspections of the Chester Street [f]acility demonstrated that *L. mono* was widespread and entrenched in the facility," and the FDA believed that additional testing was unnecessary absent some indication that aggressive cleaning and sanitization had been performed. (Second Decl. of Mary E. Losikoff ("Second Losikoff Decl.") (Doc. No. 28) ¶ 8.) Trunk also testified that his inspection was circumscribed by the fact that, unlike the August 2012 inspection, he performed the February 2013 inspection alone. (*See* Tr. 124:2–22.)

[11] Where the government seeks a statutory injunction, the Court "employ[s] a presumption of irreparable harm based on a statutory violation," *City of New York v. Golden Feather Smoke Shop, Inc.*, 597 F.3d 115, 120 (2d Cir. 2010), and the government need not offer a "specific or immediate showing of the precise way in which violation of the law will result in public harm." *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 28 (2d Cir. 1972) (citing *United States v. City & Cnty. of San Francisco*, 310 U.S. 16, 60 (1940); *Walling v. Brooklyn Braid Co.*, 152 F.2d 938 (2d Cir. 1945)); *see also Prayze FM v. FCC*, 214 F.3d 245, 248 (2d Cir. 2000).

injunctive relief.[12] However, an individual who violates the FDCA is liable only if he or she "ha[d] a responsible share in the furtherance of the transaction which the statute outlaws." *United States v. Ballistrea*, 101 F.3d 827, 836 (2d Cir. 1996) (quoting *United States v. Park*, 421 U.S. 658, 673–74 (1975) (internal quotation marks omitted)).

The government must also prove that there is a reasonable likelihood that defendants will violate the FDCA in the future unless enjoined. *See British Am. Commodity Options*, 560 F.2d at 141; *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 50. A reasonable likelihood of continued violations is "some cognizable danger of recurrent violation, [but] something more than the mere possibility which serves to keep the case alive." *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953); *cf. Blue Ribbon Smoked Fish*, 179 F. Supp. 2d at 50; *United States v. Schmitt*, 734 F. Supp. at 1049. "A likelihood of future violations may be inferred from past unlawful conduct." *British Am. Commodity Options*, 560 F.2d at 142; *Golden Feather Smoke Shop, Inc.*, 2009 WL 2612345, at *41–42.

II. Violations of the FDCA

The Court first addresses defendants' liability for the FDCA violations alleged by the government. The Court first considers whether the government has proven violations of the FDCA; if so, the Court then determines which defendants are liable for those violations.

A. Statutory Violations

In order to prove a violation of section 331(a) of the FDCA, the government must show by a preponderance of the evidence that (1) defendants' products were "food" as defined in 21 U.S.C. § 321(f); (2) defendants caused the food to be introduced or delivered for introduction into interstate commerce; and (3) defendants' food was adulterated, as defined in 21 U.S.C. §

[12] As "[t]he purpose of an injunction is to prevent future violations . . . [injunctive relief] can be utilized even without a showing of past wrongs." *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) (citing *Swift & Co. v. United States*, 276 U.S. 311, 326 (1928)) (internal citation omitted).

342(a)(4), because it was prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or rendered injurious to health. *See* 21 U.S.C. § 331(a); *see also Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 42. To prove a violation of section 331(k), the government must show that (1) defendants' products were food; (2) defendants' food or a component thereof was held for sale after shipment in interstate commerce; and (3) defendants' actions caused the food to become adulterated while held for sale. *See id.* § 331(k); *see also Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 42.

As the evidence at trial showed, since November 2012 defendants N.Y.C. Fish, Kutsyk, Roytkov, and Staroseletsky have manufactured ready-to-eat smoked and cured fishery products that constitute "food" as defined by the FDCA. *See* 21 U.S.C. § 321(f). Also since November 2012, defendants' food, which was prepared, packed, and held by defendants at the Chester Street facility, was made from ingredients received from out-of-state. As such, defendants' food products were held for sale after the shipment of a component in interstate commerce within the meaning of section 331(k). Moreover, through sales of ready-to-eat smoked and cured fishery products to stores in Maryland, Massachusetts, Pennsylvania, and New Jersey, defendants have, since November 2012, introduced and delivered for introduction into interstate commerce food within the meaning of section 331(a).

The evidence at trial also showed that defendants' food was "adulterated" in that it had "been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(4). During the most recent FDA inspection of the Chester Street facility – when the facility was operated by N.Y.C. Fish and managed by Kutsyk, Roytkov, and Staroseletsky – the FDA observed that defendants had violated the HACCP requirements for seafood processors by

failing to determine and correct the cause of critical limit deviations and by neglecting to take corrective action to ensure that affected products did not enter into commerce. *See* 21 C.F.R. § 123.7(a). Defendants further violated HACCP requirements by failing to review critical control point monitoring records to ensure that the records were complete, and neglecting to verify that the records documented values within critical limits. *See* 21 C.F.R. § 123.8(a)(3). These HACCP violations render defendants' food adulterated within the meaning of section 342(a)(4). *See* 21 C.F.R. Part 123, § 123.6(g).

The FDA also documented violations of CGMP requirements, which are suggestive of adulteration. In particular, defendants failed, in violation of 21 C.F.R. § 123.11(b), to monitor the conditions and practices during processing with sufficient frequency to ensure conformance with CGMP. Those violations were evidenced by the fact that the Chester Street facility was not constructed so that the floors, walls, and ceilings could be adequately cleaned, kept clean, and kept in good repair, and by a hole in the wall of the draining room above a processing table where fish were staged. *See* 21 C.F.R. § 110.20(b)(4). As such, the Court concludes that the government has proven violations of 21 U.S.C. §§ 331(a) and (k).

B. Individual Liability for FDCA Violations

The Court next considers which defendants are liable for the violations proven by the government.[13] As set forth in the Court's findings of fact and as explained above, the government has proven numerous violations of the FDCA.[14] The Court addresses the scope of each defendant's civil liability below.

[13] As indicated above, defendants N.Y. Fish and Koyfman have failed to appear in this action. As the government has not sought default judgments against N.Y. Fish or Koyfman and proposed findings of liability only as to the appearing defendants in this case, (*see generally* Pl.'s Proposed Findings of Fact and Conclusions of L. (Doc. No. 43)), the Court declines to make findings of liability as to the non-appearing defendants.

[14] Following trial, the government particularized the specific violations for which it alleged each defendant was responsible. (*See* Tr. at 340:20–344:22.) Defendants then submitted letters indicating which violations they

1) N.Y.C. Fish

N.Y.C. Fish was charged only with violations stemming from the February 2013 inspection. (*See* Tr. at 11:7–10.) Because a corporation bears legal responsibility for the acts and omissions of its agents and employees, *see* 21 U.S.C. § 321(e); *United States v. Dotterweich*, 320 U.S. 277, 281 (1943), N.Y.C. Fish is responsible for all acts and omissions of defendants Kutsyk, Roytkov, and Staroseletsky at the Chester Street facility in connection with those violations. N.Y.C. Fish has conceded liability for the violations with which it is charged. (Tr. at 11:11–10; *see also* Doc. No. 40.) Accordingly, the Court finds that N.Y.C. Fish is liable for all violations observed during the February 2013 inspection.

2) Kutsyk

Kutsyk was charged only with violations stemming from the February 2013 inspection. (*See* Tr. at 11:7–10.) On the basis of that inspection, the government has charged three violations of the FDCA. (*See* Pace Decl. ¶¶ 13(A)–(C).) Kutsyk contests two of those violations, arguing that he is not responsible for N.Y.C. Fish's HACCP violations because the "failures [] are attributable to the acts and/or omissions of another HACCP certified reviewer, and the applicable FDCA regulations do not require a third level of review." (Doc. No. 40 at 1.) Under the FDCA, however, "[t]he duty imposed by Congress on responsible corporate agents is . . . one that requires the highest standard of foresight and vigilance," *Park*, 421 U.S. at 673, and renders liable all persons "standing in responsible relation to a public danger." *Dotterweich*, 320 U.S. at 281 (citing *United States v. Balint*, 258 U.S. 250 (1922)).[15] Kutsyk admitted that he had

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disputed. (*See* Doc. Nos. 40–41.) The Court addresses each appearing defendant's liability based on the evidence adduced in the parties' declarations and at trial. Each defendant, however, has conceded liability for one or more violations. (*See* Doc. Nos. 13, 40–41; Tr. at 11–14.)

[15] Although *Park* and *Dotterweich* involved criminal violations of the FDCA, the principles in those cases have been applied in civil cases as well. *See, e.g.*, *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 40–42.

been trained in HACCP compliance prior to the February 2013 inspection, (*see* Tr. at 320:21–321:8), and therefore was fully aware of both the importance and the requirements of HACCP compliance. Moreover, as the sole owner and president of N.Y.C. Fish, Kutsyk had the power to prevent or correct the HACCP violations, but failed to do so. Consequently, Kutsyk is liable for those violations. *See Park*, 421 U.S. at 670–76; *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 41. The Court thus finds that Kutsyk is liable for the violations, identified above, that were observed during the February 2013 inspection.

3) Roytkov and Staroseletsky

Roytkov and Staroseletsky were charged with substantially more violations than N.Y.C. Fish and Kutsyk. (*See* Tr. at 11:20–12:20.) As detailed above, in addition to the February 2013 inspection, past FDA inspections conducted from January 2006 through August 2012 revealed consistently unsanitary conditions at the Chester Street facility, including repeated failures to implement effective sanitation controls in accordance with regulations and the sustained presence of *L. mono* in environmental samples and food products. The government charged Roytkov and Staroseletsky with over forty violations of the FDCA, stemming from the inspections performed from January 2006 through February 2013. (*See* Pace Decl. ¶¶ 12–43.) The Court finds that Roytkov and Staroseletsky are liable for all of the violations observed during that period.

Roytkov and Staroseletsky concede all but thirteen of the violations charged. (*See* Doc. No. 41.) They challenge the remaining violations primarily on the ground that they supposedly did not have the ability to control the activity, equipment, or process that is the subject of the violation. Consequently, Roytkov and Staroseletsky argue, they cannot be liable. For example, Roytkov and Staroseletsky argue that they cannot be held liable for any deficiencies in HAACP

plans, failures properly to calibrate equipment, or failures to correct plumbing or drainage problems, because they did not have control over the contents of the HAACP plans, could not retain a company to calibrate the equipment, and lacked the authority to hire a plumber. (*See id.* at 3–4.)

Even if they could not unilaterally alter HACCP materials or compel significant financial expenditures, however, their titles and duties denote significant responsibility and authority as agents of the corporation, *see Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 41 (quoting *Park*, 421 U.S. at 672), which belies their claims of powerlessness. Moreover, the provisions of the FDCA "reach and touch the individuals who execute the corporate mission" and are "by no means necessarily confined to a single corporate agent or employee." *Park*, 421 U.S. at 672. In addition to those who hold ultimate authority in a company, liability under the FDCA also attaches to "persons whose failure to exercise the authority and supervisory responsibility reposed in them by the business organization resulted in the violation" of the statute. *Id.* at 671. In that sense, "the [FDCA] punishes 'neglect where the law requires care, or inaction where it imposes a duty.'" *Id.* (quoting *Morissette v. United States*, 342 U.S. 246, 255 (1952)). As Vice President and Plant Manager at N.Y. Fish and N.Y.C. Fish from January 2006 through February 2013, Roytkov and Staroseletsky had the power to prevent or correct the violations that occurred at N.Y. Fish and N.Y.C. Fish, but failed to do so. *See Park*, 421 U.S. at 670–76; *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 41. Both were admittedly aware of the hazards posed by HACCP noncompliance. At the very least, Roytkov and Staroseletsky carried out directives and implemented policies that they knew or should have known violated existing regulations.[16]

[16] Indeed, in a signed and sworn declaration, Roytkov stated that he "take[s] responsibility for some of those lapses, as [he] was one of the individuals responsible for monitoring compliance (or lack of compliance) with HACCP and Sanitation Standard Operating Procedures (SSOP) requirements." (Roytkov Supp. Decl. (Doc. No. 31) ¶ 12.)

Roytkov and Staroseletsky also challenge several violations as unsupported by evidence in the record. (*See* Doc. No. 41 at 3.) For instance, they assert that "food residue on the equipment" at the Chester Street facility was not due to infrequent cleaning, and that "there is no factual support in the record," (*id.*), to suggest that "persons working in direct contact with food, food-contact surfaces, and food-packaging materials" failed to "store personal belongings in areas other than where food is exposed, as evidenced by personal employee food items stored in a cooler on top of pickled herring pails and raw salmon . . . ." (Pace Decl. ¶ 22(B).) The Court disagrees. Each violation is adequately established and supported by documentary evidence, including the FDA 483 inspection reports issued following the relevant inspections.[17] (*See, e.g.*, Pace Decl., Exs. 1(A), (I), (N), (O), (AN).) Accordingly, the Court finds that Roytkov and Staroseletsky are liable for all violations observed at the Chester Street facility from January 2006 through February 2013.

III. Reasonable Likelihood of Continued Violations

In addition, the government must also demonstrate a reasonable likelihood that defendants will violate the FDCA in the future unless enjoined. *See British Am. Commodity Options*, 560 F.2d at 141; *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 50. The Second Circuit has opined that "past misconduct is highly suggestive of the likelihood of future violations." *Kapps v. Wing*, 404 F.3d 105, 123 (2d Cir. 2005) (quoting *United States v. Carson*, 52 F.3d 1173, 1184 (2d Cir. 1995)). Thus, "where a history of legal violations is before the district court, that court has significant discretion to conclude that future violations of the same kind are likely." *Kapps*, 404 F.3d at 122–23 (citing *Henrietta D. v. Bloomberg*, 331 F.3d 261, 290 (2d Cir. 2003)); *see also Diapulse*, 457 F.2d at 29 (citing *W.T. Grant*, 345 U.S. at 633).

[17] With respect to two of the dispute violations, Roytkov and Staroseletsky appear to dispute whether the conditions observed were violations at all. (*See* Doc. No. 41 at 3.) Like the challenged violations discussed above, however, these too are supported by evidence in the record.

The government argues that the violations observed during the February 2013 inspection, defendants' conduct following that inspection, and Roytkov and Staroseletsky's histories of noncompliance establish a reasonable likelihood of future violations. Defendants respond that the government improperly seeks to punish N.Y.C. Fish for the failings of N.Y. Fish, and urges that changed conditions and new management are sufficient to prevent future violations.[18] Given the evidence in the record, the Court concludes that there is a reasonable likelihood that defendants will continue to violate the FDCA in the absence of injunctive relief.

At the outset, the Court notes that it gives little weight to the testimony of Kutsyk and Roytkov concerning the specific testing, training and cleaning efforts undertaken at N.Y.C. Fish. That testimony, from two individuals who have the most to lose by the outcome of these proceedings, was wholly self-serving and without any credible independent corroboration. Even taken at face value, as discussed below, their testimony does not outweigh the strong proof presented by the government regarding the risk of continuing violations. For similar reasons, and others, discussed more fully below, Costanzo's testimony proved to be of limited use, notwithstanding his qualifications as an expert in food safety and other related matters.

Turning to the merits of this question, Kutsyk's mere ownership and management of N.Y.C. Fish and the Chester Street facility does not render future violations of the FDCA unlikely. More than half of the current employees of N.Y.C. Fish were previously employed by

[18] As an initial matter, the Court notes that the issue in this case is not whether violations committed by one corporation are attributable to another. *Compare United States v. Am. Mercantile Corp.*, 889 F. Supp. 2d 1058 (W.D. Tenn. 2012). To the extent defendants suggest that any past violations committed by N.Y. Fish are irrelevant, however, defendants are incorrect. Those past violations, while not attributable to N.Y.C. Fish or Kutsyk, are relevant because (1) they bear on the physical structure of and environmental conditions initially present at the Chester Street facility; (2) N.Y.C. Fish initially adopted and implemented the same policies and procedures employed by N.Y. Fish; and (3) over half of N.Y.C. Fish's workforce is comprised of former N.Y. Fish employees who were hired ostensibly because they were "familiar with the smoked fish business, and even more so, familiar with the [Chester Street] [f]acility." (Supp. Decl. of Maxim Kutsyk (Doc. No. 33) ¶ 8.) It defies common sense to ignore prior violations that exposed the Chester Street facility to serious health hazards when evaluating defendants' steps to render that facility safe for renewed production of the same food products.

N.Y. Fish, and there is no evidence that they have been provided with training sufficient to ensure compliance with the FDCA.[19] Despite N.Y. Fish's fraught record of noncompliance, Kutsyk also adopted the HACCP and SSOP plans used by N.Y. Fish. Kutsyk then hired Roytkov and Staroseletsky, who had repeatedly failed to prevent or correct FDCA violations at N.Y. Fish, to perform substantially the same functions at N.Y.C. Fish and charged them with overseeing N.Y.C. Fish's HACCP and SSOP compliance programs. Those actions provide scant assurance that N.Y.C. Fish is properly positioned to comply with food safety regulations.

Indeed, the evidence suggests that Kutsyk has been unprepared or unwilling to take the steps necessary to ensure compliance with the FDCA. For instance, Kutsyk insists that, until the February 2013 inspection, he was ignorant of documented regulatory activity at N.Y. Fish that spanned at least six years and concerned the same facility and products his company produces. (*See* Tr. at 287:19–288:6.) Kutsyk also maintains that he blindly adopted the HACCP plans left behind by N.Y. Fish, hired N.Y. Fish's managers and employees, and re-used its equipment – all without giving any thought to whether N.Y. Fish had been compliant with the FDCA. The Court finds those assertions incredible, as even a cursory inquiry would have immediately revealed N.Y. Fish's past violations.[20] Even if Kutsyk were genuinely ignorant of the Chester Street facility's checkered past, however, the Court still could not conclude that he attempted diligently to comply with the FDCA. Kutysk testified that he gave no thought to HACCP compliance prior to the February 2013 inspection despite having received HACCP compliance training in March 2012. (Tr. at 319:15–18, 320:18–321:8.) Moreover, after adopting N.Y. Fish's HACCP plans,

[19] Although defendants insist that Costanzo has provided detailed guidance and training concerning food safety, no defendant has provided any evidence of what that training actually entailed or how the training has promoted FDCA compliance. (*See* Tr. at 227:21–228:18.)

[20] Indeed, Kutsyk needed only to have asked Roytkov and Staroseletsky. After all, both had been employed at the Chester Street facility since at least 2006 and were present during prior inspections. In fact, Kutsyk admitted at trial that Staroseletsky later produced copies of documents from those inspections. (*See* Tr. 288:7–8.)

Kutsyk proceeded for months to produce air-packed products with full knowledge that such products were not covered by those plans. (*See id.* at 299:10–25.) That conduct does not demonstrate sincere efforts to comply with the FDCA.

Moreover, given that Roytkov and Staroseletsky are functioning in essentially the same roles that they had at N.Y. Fish, and that similar violations continue at N.Y.C. Fish, there is a reasonable likelihood that those violations will continue unabated. Both defendants are responsible for numerous violations of the FDCA over many years, and the Court "may properly infer a likelihood of future violations from the defendant[s'] past unlawful conduct." *British Am. Commodity Options*, 803 F.2d at 1251. Roytkov pays lip service to the fact that he is now "committed to food safety and assure[s] the Court that under the changed circumstances resulting from a new business and new owner, [he] [is] now able to help implement practices and procedures to comply with FDCA regulations." (Roytkov Decl. (Doc. No. 18) ¶ 17.) Similarly, Staroseletsky states that Costanzo has directed him "to keep much more detailed records of food safety compliance, which [he] [is] doing," and avers that he is "committed to food safety and believe[s] that with Mr. Kutsyk's hand-on [*sic*] approach, the business's firmer financial condition, and Mr. Costanzo's expertise we are now able to operate [N.Y.C.] Fish in substantial compliance with FDCA regulations." (Staroseletsky Decl. (Doc. No. 19) ¶¶ 16, 18.) These naked assertions are wholly unsubstantiated and lack credibility, particularly given Roytkov and Staroseletsky's track records.[21]

Both Roytkov and Staroseletsky have consistently squandered opportunities to correct their failures to adhere to safety regulations. Despite explanations of recurring violations offered

[21] Staroseletsky's assurances are especially unconvincing in light of his cavalier disregard of food safety precautions in the past. During the August 2012 inspection, Staroseletsky stated that he could determine – merely by visual inspection – whether a batch of product had been cooked at the correct temperature and for the correct amount of time. (Decl. of Peter M. Trunk ("Trunk Decl..") (Doc. No. 30) ¶ 24.) That is a troubling departure from the requirements of N.Y. Fish's HACCP plan and the requirements of the FDCA.

by FDA investigators and training from past consultants about how to remedy those violations, they have repeatedly failed to prepare and review crucial records, correct unsanitary conditions, and prevent violations of the FDCA. (*See* Losikoff Supp. Decl. (Doc. No. 28) ¶ 14.) Neither Roytkov nor Staroseletsky has provided convincing evidence of better training, the implementation of new safety procedures, or other observable steps that will ensure their compliance. And their conduct thus far does not inspire much confidence. Although both Roytkov and Staroseletsky portray their past conduct largely as the result of Koyfman's reluctance to make necessary changes or N.Y. Fish's lack of funds, their continued noncompliance at N.Y.C. Fish – where they maintain their safety concerns *are* taken seriously – undermines their suggestion that past violations were the products of Koyfman's reticence or N.Y. Fish's financial weakness.[22] For example, from November 2012 through January 2013, Staroseletsky prepared time and temperature logs for batches of cooked fish that did not match the time and temperature recording charts of the ovens. Roytkov then signed the logs without reviewing or verifying their accuracy. (Trunk Decl. ¶ 14.) This conduct persisted despite prior warnings from FDA investigators and defendants' change of employer. (*See* Second Losikoff Decl. ¶ 11; Third Declaration of Mary E. Losikoff ("Third Losikoff Decl.") (Doc. No. 42-1) ¶ 2; Pace Decl., Ex. 1(A) at 20, 22.) In light of their past history of violations – both at N.Y. Fish and at N.Y.C. Fish – and the lack of any proof demonstrating real change, there is a reasonable likelihood that Roytkov and Staroseletsky will continue to violate the FDCA.[23]

[22] Moreover, not all of the violations observed by the FDA can be so characterized. Roytkov concedes as much. (*See* Supp. Decl. of Pavel Roytkov (Doc. No. 31) ¶ 12.)

[23] Kutsyk states that, as a result of this litigation, he has relieved Staroseletsky and Roytkov of the responsibility to certify HACCP and SSOP records. (Supp. Decl. of Maxim Kutsyk ¶¶ 51–53.) However, that is insufficient to assuage concerns about FDCA noncompliance. First, there is no indication that their removal from the certification process is anything but temporary. Second, as Losikoff testified and as the facts amply demonstrate, managers have far more responsibilities with respect to HACCP compliance than simply certifying records. (*See* Tr. at 202:25–203:20.) According to Costanzo, Roytkov and Staroseletsky still remain involved with all other aspects of ensuring that N.Y.C. Fish produces safe products. (*See id.* at 248:14–21.)

The retention of Costanzo as a consultant is hardly sufficient to ensure future compliance with the FDCA. At trial, Costanzo described his approach to sanitation and FDCA compliance as "stepwise," explaining that

> We develop sanitation programs. We implement them. We move on to testing[,] which is a verification step to verify that these cleaning and sanitizing services are working. Then we document what we're doing. The danger here is that you rush in to putting this stuff in writing and then when an inspector shows up, well, what you're doing doesn't match what you say you're doing, that is to say the written component. So, in my view, the written component should follow along what you've actually established. So, you know, I think that a mistake many people make is, first, coming up with this idealized version of a cleaning and sanitizing program and turning your people loose and it turns out that what they're doing has no bearing on what the written component says.

(Tr. at 233:16–234:8.) Costanzo also agreed that, in essence, "it's what the people are going to ultimately be doing that's going to determine what goes into the SSOP." (*Id.* at 237:13–16.) That gets the process backwards. Regulations and model sanitation procedures are designed to guide employees' actions, not be dictated by them. Here, over half of N.Y.C. Fish's employees formerly worked at N.Y. Fish, a company with a long history of serious FDCA violations. N.Y.C. Fish then adopted N.Y. Fish's HACCP and SSOP plans, which were concededly inadequate and, in any event, not followed. At the February 2013 inspection, the FDA observed unsanitary conditions and documented violations by N.Y.C. Fish employees. Apart from Kutsyk, Roytkov, and Staroseletsky, it appears that no N.Y.C. Fish employees have been provided with any training by Costanzo. It is therefore difficult to see how conforming an SSOP to what N.Y.C. Fish employees are actually doing will prevent additional violations of the FDCA, when those very employees have violated the FDCA.

Finally, the changes defendants have allegedly already made will not render the Chester Street facility safe for seafood production. Defendants repeatedly emphasize that they have made repairs to the facility and its equipment, revised HACCP plans, purchased new cleaning

supplies, and installed new cleaning systems. While all parties acknowledge that such changes may be beneficial, those improvements merely address violations actually documented by the FDA to attempt to bring the facility into compliance with CGMP.[24] (Tr. at 173:1–175:21.) But Losikoff testified at trial that "basic GMPs [or good manufacturing practices] are not going to eradicate the *listeria* problem within the facility," characterizing the steps taken by defendants as "what is done in a regular plant that has no other problems."[25] (Tr. at 173:21–174:4.) According to Losikoff, defendants have not "adopted aggressive sanitation and environmental monitoring programs to ensure that the widespread and entrenched *Listeria monocytogenes* . . . colonization in the Chester Street [f]acility is eliminated," "provided adequate assurances that they will implement the remedial efforts they have professed to have undertaken," or "taken adequate steps to re-train the N.Y. Fish hold-over employees." (Second Losikoff Decl. ¶ 2.) Losikoff stated that

> FDA testing in 2006, 2008, 2009, 2010, and 2012 found *L. mono* in numerous locations within the Chester Street [f]acility. In 2012 alone, *L. mono* was detected throughout the facility in the rinse/hanging room, cutting/cleaning room, and the packing room. The *L. mono* contamination in the facility led to *L. mono*-contaminated smoked fish products that were distributed in interstate commerce. FDA testing in 2008, 2009, and 2012 revealed *L. mono* in samples of the in-process and finished fish products collected not only from the Chester Street Facility, but also from retailers in two cities in Illinois and one city in Pennsylvania.

[24] That defendants may have remedied the violations documented during a formal inspection is not necessarily a reliable indicator of an improved commitment to food safety. The FDA's regulatory scheme contemplates that a regulated entity will proactively take corrective action immediately upon the occurrence of a *deviation* from the HACCP, not after the FDA has *documented* that deviation during a later inspection. (*See* Tr. at 198:6–199:23.)

[25] The Court notes that Costanzo maintains the new cleaning systems are sufficient to combat the *L. mono* infestation at N.Y.C. Fish. Costanzo, however, may have a personal interest in so testifying because he sells those very products. (*See* Costanzo Decl. ¶¶ 18–20.) The Court instead credits Losikoff's testimony that "[t]hese types of systems may be useful on a daily basis for treating food processing equipment, provided that the food processing equipment is adequately cleaned," but that they are not "a sanitation panacea, and no matter how they are used, they will not, in and of themselves, eliminate the *L. mono* entrenched in the Chester Street [f]acility." (Second Losikoff Decl. ¶ 7.) Moreover, as Losikoff notes, defendants have not explained the significance of the systems to their overall sanitation scheme or even "described whether these systems will be used to treat product, water, or equipment . . . ." (*Id.*)

(*Id.* ¶ 3.) In the FDA's view, such a serious bacterial infestation indicates that "[t]he *L. mono* in the Chester Street [f]acility is not a transient population . . . that can be eliminated through daily, ordinary sanitation and cleaning procedures" and requires "aggressive sanitizing and cleaning" of the facility to ensure that future food products are not contaminated as well. (*Id.* ¶¶ 3–4.) Losikoff also testified that, in her experience, few facilities exhibit the level of *L. mono* contamination found at the Chester Street facility, which she characterized as "one of the most serious that [she has] encountered." (Tr. at 145:5–8, 160:17–18.) Given the severity of that contamination, Losikoff maintains that defendants have not developed or implemented a sufficiently aggressive sanitation program to combat the serious bacterial colonization in the Chester Street facility, nor have they developed or instituted an effective program for monitoring and testing the facility and food for *L. mono*. (Second Losikoff Decl. ¶ 4; Tr. at 157:8–162:14.)

At trial, Constanzo agreed that an aggressive sanitation program was necessary to eliminate entrenched *L. mono* contamination. (*See* Tr. at 222:24–223:5; 224:7–12.) And he conceded that *L. mono* may even be entrenched at the Chester Street facility. (*See id.* at 248:8–10.) But Costanzo painted a different picture of what constitutes an aggressive sanitation program; whereas Losikoff recommended disassembling equipment and soaking the components overnight in sanitizing solutions, applying hot steam to larger machinery, and fogging rooms with sanitizing chemicals, Costanzo stated that he believes hosing down the walls with hot water, scrubbing the walls and floor, and applying a foam sanitizer is sufficient. (*See* Losikoff Decl. ¶ 74; Tr. at 240:25–241:12.)

The Court gives little weight to Costanzo's testimony in this regard. Costanzo's opinions are based purely on his observations of defendants' alleged current cleaning and sanitizing routines, and not on any actual testing for *L. mono*. (Tr. at 226:10–21.) In fact, Costanzo

conceded that he could not say that the *L. mono* previously found at the Chester Street facility had been eradicated by the cleanings that were performed or the processes he had instituted. (*Id.* at 243:12–20.) Costanzo is present at the Chester Street facility only one day per week to supervise defendants' operations and, at trial, could not describe what training would be adequate to ensure FDCA compliance by Kutsyk, Roytkov, and Staroseletsky. (*Id.* at 228:19–229:6.) The training Costanzo *has* provided consisted of "spending five hours . . . basically talking to people, watching what they do, making comments on how to conduct yourself, how to handle product, how to keep your hands clean, [and] how to keep food contact surfaces clean." (*Id.* at 230:6–16.) Moreover, all training was purely verbal.[26] Indeed, Costanzo has declined to craft any written training materials, SSOPs, environmental monitoring programs, sanitation control programs, or remedial plans should *L. mono* be discovered, because he believes that a written plan and "both environmental and finished product testing" would be premature. (*Id.* at 234:15–23; 253:2–15.) Despite the lack of any written materials to disseminate, Costanzo indicated that he has provided training only to Kutsyk, Roytkov, and Staroseletsky, and not to any other employees of N.Y.C. Fish. (*Id.* at 249:16–18.)

The goal and "overriding purpose" of the FDCA is to "protect the public health" by enforcing standards of purity and effectiveness. *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969); *see also Diapulse*, 457 F.2d at 28. The Court has not been provided with any credible evidence that N.Y.C. Fish has improved its approach to food safety. In fact, given Costanzo's "stepwise" approach and his concession that many steps remain to be taken, the Court cannot even be certain that N.Y.C. Fish is *currently* in compliance with the

[26] Notably, Costanzo also testified that the average written SSOP is approximately twenty-five pages in length. (Tr. at 235:21–236:7.)

FDCA.[27] (Tr. at 250:17–20.) The government has demonstrated numerous violations by each defendant of the FDCA and offered considerable and persuasive evidence that violations are likely to persist. Defendants efforts to demonstrate new circumstances, policies, or practices likely to prevent future violations are not credible, and do not in any way rebut the strong evidence that such violations will continue. Based on the evidence in the record, the Court concludes that, absent an injunction, there exists a reasonable likelihood that the violations documented by the FDA will recur. Accordingly, the government is entitled to a permanent injunction.

IV. Scope of the Injunction

To remedy a reasonable likelihood of future violations, an injunction "may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur," *Diapulse*, 457 F.2d at 29 (citing *May Dep't Stores Co. v. NLRB*, 326 U.S. 376 (1945)), and "the FDA has broad authority in matters involving adulterated products which can damage the health of the public." *United States v. Blue Ribbon Smoked Fish, Inc.* ("*Blue Ribbon II*"), 56 F. App'x 542, 543 (2d Cir. 2003). Moreover, "when Congress has integrated traditional modes of equitable relief into a statutory enforcement scheme, the [C]ourt's equitable power should be exercised in harmony with the overall objectives of the legislation." *Commodity Futures Trading Comm'n v. Hunt*, 591 F.2d 1211, 1219 (7th Cir. 1979) (citing *SEC v. Advance Growth Capital Corp.*, 470 F.2d 40, 53 (7th Cir. 1972)); *accord United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1017 (E.D. Cal. 2010); *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp.

[27] The samples allegedly tested by N.Y.C. Fish, subsequent to the February 2013 inspection and discussed at trial, even if accurate, are insufficient to show that *L. mono* is no longer present at the Chester Street facility. Although the samples allegedly tested negative for *L. mono*, there is no evidence that the samples were taken from the locations where *L. mono* had repeatedly been detected in the past. In fact, there is no evidence whatsoever as to when, where, or how the samples were collected.

2d at 51. The Court thus has considerable discretion in crafting an injunction in this context. *See Blue Ribbon II*, 56 F. App'x at 543.

In general, the fact that an injunction may put a party out of business is irrelevant, for there is "no vested interest in a business activity found to be illegal." *Diapulse*, 457 F.2d at 29 (citing *United States v. Walsh*, 331 U.S. 432 (1947)) (internal quotations and alterations omitted); *cf. Blue Ribbon Smoked Fish*, 179 F. Supp. 2d at 50 (citing *Diapulse*, 457 F.2d at 29) ("The Second Circuit has held that a business may not complain 'that the injunction is impermissible because it will put him out of business.'"). Nor do defendants' representations that they intend to comply with the FDCA preclude granting an injunction. *See United States v. W. Serum Co., Inc.*, 498 F. Supp. 863, 868 (D. Ariz. 1980), *aff'd*, 666 F.2d 335 (9th Cir. 1982) (citing *United States v. Article of Drug . . . B Cholinos Capsules*, 362 F.2d 923, 928 (3d Cir. 1966); *United States v. Medwick Labs., Inc.*, 416 F. Supp. 832, 833 (N.D. Ill. 1976)). Nevertheless, there are limits to injunctive relief, which "should be narrowly tailored to fit specific legal violations." *Blue Ribbon II*, 56 F. App'x at 543 (quoting *Society For Good Will To Retarded Children, Inc. v. Cuomo*, 737 F.2d 1239, 1251 (2d Cir. 1984)) (internal alteration omitted).

With these concerns in mind, the Court raised questions regarding specific provisions of the government's proposed injunction, which the parties were directed to address in their post-trial briefs. (*See* Tr. at 330–333.) The government maintains that its proposed permanent injunction is necessary to ensure compliance with the FDCA, while defendants contend that the government's proposed permanent injunction is too broad. Specifically, defendants cite *United States v. American Mercantile Corporation*, No. 11-CV-2371 (STA) (CGC), 2012 WL 5457355 (W.D. Tenn. Nov. 8, 2012), and argue that courts have found injunctions like the government's

proposed order to be "overbroad and unnecessary" in cases "where a defendant has already taken remedial measures." (Mem. of L. by Defs. Roytkov & Staroseletsky (Doc. No. 48) at 17; *see also* Mem. of L. by Defs. N.Y.C. Fish & Kutsyk (Doc. No. 45) at 17–19.) According to defendants, in *American Mercantile*, as here, "[t]he government argued . . . that the evidence of each [d]efendant's past violations [wa]s simply the best indication of the likelihood of future violations" and further "emphasized that [d]efendants ha[d] a proven track record of violations, demonstrating that they cannot achieve compliance with the law on their own." 2012 WL 5457355, at *3. Under those circumstances, the government argued, the "[d]efendants' promises of improvement r[a]ng hollow in light of their inability to correct the same recurring issues over time." *Id.* Defendants here note that the court found certain elements of the government's requested injunctive relief were not warranted in light of steps those defendants had already taken to improve conditions at their facilities. Defendants urge that a similar outcome is warranted here. Not so.

In *American Mercantile*, the facility in question – which had been renovated for months immediately prior to the commencement of operations on the premises – had undergone three inspections by three different entities, with no finding of any violations. *See id.* at *4. One defendant in *American Mercantile* also "changed its business significantly, moving away from food handling and processing to simple distribution" and "no longer t[ook] physical possession of its inventory at all." *Id.* at *5. Moreover, all of the defendants in *American Mercantile* had "made a number of investments to improve their operations since the last FDA inspection . . . changes the government ha[d] no evidence to controvert." *Id.* at *4.

The record in this case is very different. Far from being extensively renovated to address health concerns, the Chester Street facility apparently sat vacant for a month before N.Y.C. Fish

commenced operations, and at best defendants claim to have cleaned the facility and fixed problems obviously in need of repair.[28] Additionally, defendants in this case *claim* to have made a number of investments, but failed to offer credible evidence to substantiate the effectiveness of any improvements. For example, there is no evidence concerning the actual existence or effectiveness of any new environmental monitoring systems, SSOP guidelines, or sanitation control programs ostensibly implemented by Costanzo. And the government has produced evidence that, even assuming defendants *have* made the changes they claim, those changes are not enough to remedy the most serious issues highlighted by the FDA. The facts of this case – and these defendants – are a far cry from those in *American Mercantile*. Furthermore, it is worth noting that, despite all of the salutary efforts made by the defendants in that case, the court *still* found a likelihood of recurrent violations on the facts before it. *See* 2012 WL 5457355, at *5–6.

Two other issues merit mention. Although courts routinely enjoin both corporate officers and corporate entities in FDCA cases, *see Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 41, fundamental equitable concerns require a distinction between the corporate entities and individual defendants in this case. *Cf. Blue Ribbon II*, 56 F. App'x at 544 (limiting provisions of an injunction concerning corporate officers to activity associated with the production facility at issue). The government's original proposed order did not address the provisions of its proposed injunction that would restrain "each and all of [each defendant's] directors, officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any persons in active

[28] As the government notes, (*see* Pl.'s Post-Trial Reply Br. at 10–11), defendants only belatedly suggested in a supplemental declaration by Kutsyk that the Chester Street facility had been cleaned prior to N.Y.C. Fish commencing operations, and there is no other evidence to support his assertion. The other remedial measures Kutsyk trumpets are deficient as well. For instance, after the February 2013 inspection Kutsyk notified the FDA that a product found to have an incorrect water phase salt content during the inspection was air-packed, and therefore subject to a lower critical limit. (*See* Kutsyk Decl. ¶¶ 29–38.) Even assuming such proof was provided, however, it does not obviate the violation because the HACCP plan in place at that time did not contemplate the production of air-packed products and there is no evidence that any N.Y.C. Fish employees were trained to produce such products. (*See* Tr. at 187:2–15.)

concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships)," regardless of whether those persons or entities receive notice of the injunction or have any connection to food produced by N.Y. Fish or N.Y.C. Fish at the Chester Street facility. (Doc. No. 38-1) ¶ V.) The government's proposed alternative language, (*see* Pl.'s Post-Trial Reply Br. (Doc. No. 54) at 18), appears adequately to address this concern.

Second, as noted above, defendants N.Y. Fish and Koyfman have failed to appear or otherwise respond throughout this litigation. The government has not moved for default judgments against the non-appearing defendants or proposed findings of liability as to them, yet the proposed permanent injunction seeks to enjoin *all* defendants in this action – including N.Y. Fish and Koyfman. (*See id*. at 1.) The government's post-trial memoranda offer no explanation and contain no legal authority justifying an injunction as to these parties in the absence of findings as to their liability and a likelihood of future violations. As such, the proposed permanent injunction is overbroad insofar as it concerns the non-appearing defendants, and the injunctive relief will be limited to the appearing defendants.

CONCLUSION

For the foregoing reasons, defendants' motions for leave to submit additional evidence (Doc. Nos. 47, 58) are denied. The government's motion for injunctive relief (Doc. No. 2) is granted consistent with this Memorandum and Order.

The government is directed to transmit forthwith a copy of this Memorandum and Order and the accompanying Order of Permanent Injunction to all non-appearing defendants, and file a letter with the Court indicating that it has so done.

SO ORDERED.

Roslynn R. Mauskopf

Dated: Brooklyn, New York
March 30, 2014

ROSLYNN R. MAUSKOPF
United States District Judge